



U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE

INFORMATION DISCLOSURE STATEMENT

Docket Number:
1662/52804

Application Number
10/759,573

Filing Date
January 16, 2004

Examiner
Simon J. Oh

Art Unit
1618

Invention Title
STABLE GABAPENTIN HAVING pH WITHIN A
CONTROLLED RANGE

Inventor(s)
Claude SINGER et al.

Address to

Mail Stop: RCE

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to:

Mail Stop: RCE

Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450

on

Date: Sept - 1, 2005

Signature: Josephine Hardy
JOSEPHINE HARDY

Sir:

1. In accordance with the duty of disclosure under 37 C.F.R. § 1.56 and in conformance with the procedures of 37 C.F.R. §§ 1.97 and 1.98 and M.P.E.P. § 609, attorneys for Applicants hereby bring the following references to the attention of the Examiner. The references are listed on the attached modified PTO Form No. 1449. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.
2. The filing of this Information Disclosure Statement and the enclosed PTO Form No. 1449, shall not be construed as an admission that the information cited is prior art, or is considered to be material to patentability as defined in 37 C.F.R. § 1.56(b).
3. A copy of each non-U.S. patent, non-U.S. published application, unpublished U.S. application, non-patent publication, or other information listed on the modified PTO form 1449 is enclosed.
4. It is believed that no fees are due in connection with this Information Disclosure Statement. However, should any fees be due, the Commissioner is authorized to charge Deposit Account No. 11-0600 for such fees. A copy of this communication is enclosed for charging purposes.

Dated: 9/1/05

By: Craig L. Puckett

Craig L. Puckett (Reg. No. 43,023)

KENYON & KENYON

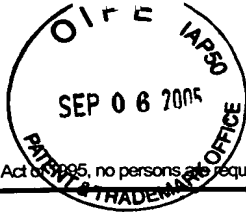
One Broadway

New York, N.Y. 10004

(212) 425-7200 (telephone)

(212) 425-5288 (facsimile)

CUSTOMER NO. 26646



Substitute for form 1449A/PTO

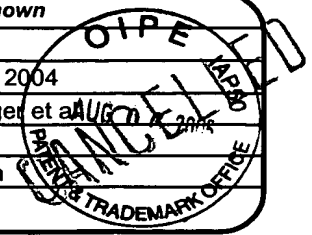
**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet 1 of 2

Complete if Known

Application Number	10/759,573
Filing Date	January 16, 2004
First Named Inventor	Claude Singer et al.
Art Unit	1615
Examiner Name	Simon J. Oh
Attorney Docket Number	1662/52804

**U.S. PATENT DOCUMENTS**

Examiner Initials *	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code ² (if known)			
		5,095,148	March 10, 1992	Mettler et. al.	
		5,510,381	April 23, 1996	A.C. Pande	
		5,149,870	September 22, 1992	Mettler et al.	
		5,136,091	August 4, 1992	Mettler et al.	
		5,130,455	July 14, 1992	Mettler et al.	
		5,095,148	March 10, 1992	Mettler et al.	
		6,765,114	July 20, 2004	Gizur et al.	
		6,528,682	March 4, 2003	Bosch Llado et al.	
		6,294,690	September 25, 2001	Deering et al.	

FOREIGN PATENT DOCUMENTS

Examin er Initials *	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³ - Number ⁴ - Kind Code ⁵ (if known)				
		DE 24 80 891	July 1, 1976	Satzinger et al.		Yes (Abs.)
		EP 0 458 751 A1	Nov. 27, 1991	Cherukuri et al.		
		WO 97/33858	Sept. 18, 1997	Horwell et al.		
		GB 898 692	June 14, 1962	Warner Lambert		
		WO 04/46108	June 3, 2004	Kuppuswamy et al.		
		WO 00/01660	January 13, 2000	Paicocchi et al.		
		WO 02/34709	May 2, 2002	Cannata et al.		
		WO 00/39074	July 6, 2000	Gizur et al.		
		WO 00/64857	November 2, 2000	Bosch Llado et al		
		WO 99/18063	April 15, 1999	Deering et al.		
		WO 96/36328	July 22, 1999	Pande		
		WO 92/14443	September 3, 1992	Chaturvedi et al.		

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

Substitute for form 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)		Complete if Known	
		Application Number	10/759,573
		Filing Date	January 16, 2004
		First Named Inventor	Claude Singer et al.
		Art Unit	1615
		Examiner Name	Simon J. Oh
		Attorney Docket Number	1662/52804
Sheet		of	

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		Zour et al. "Stability studies of gabapentin in aqueous solutions" <i>Pharmaceutical Research</i> , Vol. 9, No. 5, 1992 pages 595-600	
		USP Monograph for Gabapentin Pharmacopeial Forum, Vol. 25, No. 5, Sept.-Oct. 1999, pages 8711-8717	
		Holder, R.W. et al., "Geminate-Substituted Cyclopentadienes. 1. Synthesis of 5,5-Dialkylcyclopentadienes via 4,4-Dialkylcyclopent-2-en-1-ones", <i>J. Org. Chem.</i> 1982, Vol. 47, pages 1445-1451.	
		Thorpe et al.; paper entitled, "The Formation and Reactions of Imino Compounds: Part XVIII. The Condensation of cycloHexanones with Cyanoacetamide Involving the Displacement of an Alkyl Group. <i>J. Chem. Soc.</i> 1913, pages 1586-1600.	
		Vogel, A.I., paper entitled "Physical Properties and Chemical Constitution: Part II. Esters of γ -Substituted Glutaric Acids. <i>J. Chem. Soc.</i> , 1934, pages 1758-1765	
		Griffiths et al., "Novel Synthesis of Gabapentin via Addition of Hydrocyanic Acid to Cyclohexylidenemalonate or Cyano(cyclohexylidene) acetate," <i>Helvetica Chimica Acta</i> , 74, 309 (1991)	
		Kearney et al., "The Effect of Cyclodextrins on the Rate of Intramolecular Lactamization of Gabapentin in Aqueous Solution," <i>International Journal of Pharmaceutics</i> , 78, 25-34 (1992).	
		Notice of Opposition to A European Patent, No. 1 289 364 of Teva Pharmaceutical Industries Ltd., Opponent: Hikal Limited, 10 December 2003, European Patent Bulletin, pp. 1-4; and Statement of Grounds for Opposition, pp. 1-16.	
		Arrow Generics Limited and Teva Pharmaceutical Industries Limited, Amended Grounds of Invalidity, In the High Court of Justice Chancery Division Patents Court, Case No. HC 04 C 00951, 16 March 2004, pp. 1-3.	
		Teva Pharmaceutical Industries Limited and Generics (UK) Limited, Defence and Counterclaim, In the High Court of Justice Chancery Division Patents Court, Case No. HC 04 C 03383, 17 December 2004, pp. 1-2 and pp. 1-3.	
		Teva Pharmaceutical Industries Ltd. v. Hikal Group Ltd., Civil Action No. 1:05-cv-00691 (ESH), In the United States District Court for the District of Columbia, Answer, Affirmative Defenses, Counterclaim and Jury Trial Demand of Defendants Apotex Corp. and Apotex Inc., May 16, 2005, pp. 1-59.	
		Teva Pharmaceutical Industries Limited and Generics (UK) Limited, Grounds of Invalidity, In the High Court of Justice Chancery Division Patents Court, Case No. HC 04 C 03383, 17 December 2004, pp. 1-3.	
		Request for Examination Under Section 35(1) of the Act and Request for Advanced Examination Under Section 28 of the Rules in Teva Pharmaceutical Industries' Canadian Patent Application No. 2,411,787, to Commissioner of Patents (Canada) by Kirby Eades Gale Baker on May 27, 2005, pp. 2-14, (incl. Appendix A, 12 pages, Appendix B, 1 page, Appendix C, 5 pages.)	
		Complaint, of Teva Pharmaceutical Industries Ltd. against Hexal AG and Salutas Pharma GmbH, Regional Court Dusseldorf, 4 th Civil Chamber, October 20, 2003, pp. 10.	

		Complaint, of Teva Pharmaceutical Industries Ltd. against ratiopharm GmbH and Merckle GmbH, Regional Court Dusseldorf, 4 th Civil Chamber, October 20, 2003, pp. 10.	
		Complaint, of Teva Pharmaceutical Industries Ltd. against STADapharm GmbH and STADA Arzneimittel AG, Regional Court Dusseldorf, 4 th Civil Chamber, October 20, 2003, pp. 10.	
		Complaint, of Teva Pharmaceutical Industries Ltd. against Zambon Group SpA (Italy) and Zambon GmbH, Regional Court Dusseldorf, 4 th Civil Chamber, October 20, 2003, pp. 10.	
		Reply and Counterclaim Brief of Teva Pharmaceutical Industries Limited, and Zambon Group SpA, Court of Milano, Section specialized in intellectual and industrial property matters, Case No. 77571/03, February 7, 2004, pp. 1-14.	
		Writ of Summons, Court of Milan, Zambon Group SpA and Teva Pharmaceutical Industries Ltd., Milan, December 9, 2003, pp. 1-21.	
		Brief of Reply for the Plaintiff, Court of Milano, Section Specialized in Industrial Right I.J. Dr. Migliaccio In the Lawsuit No. 77571/02 brought by Zambon Group SpA against Teva Pharmaceutical Industries Ltd., Milan, June 15, 2004, pp. 1-15.	

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.